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ENFORCEMENT RESPONSE POLICY FOR THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT GOOD LABORATORY PRACTICE (GLP) REGULATIONS

Office of Compliance Monitoring
Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency

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ENFORCEMENT RESPONSE POLICY FOR THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT GOOD LABORATORY PRACTICE (GLP) REGULATIONS

INTRODUCTION

This policy sets forth the procedures that will be used to determine the appropriate enforcement response for violations for the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Good Laboratory Practice Standards (GLPs) found at 40 CFR Part 160. This policy is a supplement to the July 2, 1990 FIFRA Enforcement Response Policy (ERP) and is to be used in conjunction with the policies and matrices found in that ERP.

The EPA relies on data submitted by registrants as the basis for the Agency's regulatory decisions involving pesticide product registrations, tolerances, experimental use permits, special local needs registrations, emergency exemptions, or any other research or marketing permit for a pesticide (hereafter referred to as "research or marketing permits"). In conjunction with the EPA's data audit program, the FIFRA GLPs are intended to ensure the quality and integrity of this data.

Violations of the FIFRA GLPs may impact: (1) the reliability or scientific merits of test data; (2) the ability of the EPA to validate or reconstruct test results; (3) the ability of the Agency to make sound and timely regulatory decisions regarding a pesticide; and, (4)

the EPA's administration of the GLP inspection and enforcement program. Therefore, noncompliance with the FIFRA GLP regulations may result in very serious harm to the EPA's regulatory mission and, ultimately, human health and the environment.

Violations of the FIFRA GLPs may involve violations of FIFRA sections 12(a)(2)(B)(i), 12(a)(2)(M), 12(a)(2)(Q), or 12(a)(2)(R). Appropriate enforcement responses for violations of the FIFRA GLPs include notices of warning, civil penalties of up to $5,000 per offense, and criminal penalties. In addition to these enforcement responses, the EPA may take regulatory action for violations of the GLPs, including: rejection of studies which do not comply with the FIFRA GLPs; cancellation, suspension, or modification of a pesticides research or marketing permit; or denial or disapproval of an application for such a permit. Further, in order to help assure that the Federal Government is dealing with responsible contractors, and for the purposes of the Federal Government's protection, pesticide testing facilities responsible for significant or major GLP violations may also be suspended or debarred from Government contracts or subcontracts. To address these types of action, this policy includes a section on referrals to other EPA offices.

REQUIREMENTS OF THE FIFRA GLPS

The FIFRA GLP standards, found at 40 CFR Part 160, prescribe the minimum requirements that a pesticide testing facility (i.e., the laboratory, field site, etc.) and the sponsor must fulfill in the following areas:

1. Organization and personnel.
2. Facilities.
3. Equipment.
4. Testing facilities operation.
5. Test, control, and reference substances.
6. Protocol for and conduct of a study.
7. Records and reports.

Regulated Community

Any person, including a sponsor, pesticide testing facility, or registrant, who conducts, initiates, or supports a study required by the Agency under FIFRA sections 3, 4, 5, 18, or 24(c), or sections 408 or 409 of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Liability

The EPA may pursue enforcement actions for violations of the FIFRA GLPS against any of the persons listed above depending on the specific facts of the case. Generally, the EPA will pursue separate civil administrative enforcement actions against the study sponsor, applicant for the research or marketing permit, and the pesticide testing facility since each of these parties have affirmative obligations to assure a study complies with the GLP regulations. If the sponsor, applicant of the research or marketing permit, or the pesticide testing facility are the same entity, the EPA will generally pursue a single enforcement action against that single entity. The signers of the GLP compliance statement may also be liable as individuals if the compliance statement required by 40 CFR 160.12 is false. However, in most cases, EPA will pursue enforcement actions against the company for which those individuals are employees or Agents.

Studies Covered Under the FIFRA GLPs

The FIFRA GLPs, as published in the Federal Register on November 29, 1983 (48 FR 53946), apply to all studies performed to determine the toxicity, metabolism, or other effects in humans and domestic animals which were conducted, initiated, or supported on or after May 2, 1984. 1/

The FIFRA GLPs, as amended (August 17, 1989; 54 FR 34052), also apply to all studies performed to determine the effects, metabolism, product performance (with the exception of certain efficacy studies), environmental and chemical fate, persistence and residue, or other characteristics in humans, other living organisms, or media, conducted, initiated, or supported on or after October 16, 1989. 1/

1/ The term "supported" includes studies which have been submitted to the EPA after the effective date of the GLP regulations. Therefore, studies which have been conducted or initiated before the effective date, but have been submitted to the EPA in support of a pesticide product research or marketing permit after the effective date, must be submitted with the GLP Compliance Statement required by 40 CFR 160.12.

As per the scope of the GLP regulations found at 40 CFR 160.1 and the definition of a "research or marketing permit" found in 40 CFR

160.3, the FIFRA GLP standards apply to all studies as defined above which are performed to support: (1) an application for registration, amended registration, or re-registration of a pesticide product under FIFRA sections 3, 4, or 24(c); (2) an application for an experimental use permit under FIFRA section 5; (3) an application for an emergency exemption under FIFRA section 18; (4) a petition or other request for establishment or modification of a tolerance, for an exemption for the need for a tolerance, or for other clearance under FFDCA section 408; (5) a petition or other request for establishment or modification of a food additive regulation or other clearance by EPA under FFDCA section 409; (6) a submission of data in response to a notice issued by EPA under FIFRA section 3(c)(2)(B); or (7) any other application, petition, or submission sent to EPA intended to persuade EPA to grant, modify, or leave unmodified a registration or other approval required as a condition of sale or distribution of a pesticide.

Violations

Violations of the FIFRA GLP Standards will be charged as unlawful acts of FIFRA under sections 12(a)(2)(B)(i), 12(a)(2)(M), 12(a)(2)(Q), or 12(a)(2)(R). The determination of the appropriate unlawful act to charge a violator will depend on the specific facts of the case, based on the following guidance.

Violations of the GLPs Related to a False GLP Compliance Statement - FIFRA Sections 12(a)(2)(M) and 12(a)(2)(Q)

Under 40 CFR 160.12, any person who submits to EPA data from a study which falls under the scope of the GLPs must submit a statement, signed by the applicant of the pesticide product research or marketing permit, the sponsor, and the study director, that: (1) the study complies with the GLP requirements; (2) describes the differences between the practices used in the study and those required by the FIFRA GLPs; or (3) the person was not the sponsor of the study, did not conduct the study, and does not know whether the study complies with the FIFRA GLP requirements. If a study is submitted to EPA with a GLP compliance statement which states that the study complies with the GLP requirements, and GLP violations have occurred, then EPA will consider that compliance to be false. Similarly, if a study is submitted to EPA with a GLP compliance statement which incorrectly describes the differences between the practices used in the study and those required by the GLPs, then EPA will also consider the compliance statement to be false.

Submission of a false compliance statement is a violation of FIFRA section 12(a)(2)(M) or FIFRA section 12(a)(2)(Q). If the statement was knowingly falsified, EPA may issue a civil penalty for a violation of FIFRA section 12(a)(2)(M) or pursue a criminal action. Otherwise, submission of a false GLP compliance statement will be pursued as a violation of FIFRA section 12(a)(2)(Q), as either a "high level," "middle level," or "low level" GLP violation (see Appendix GLP-A for gravity levels and Appendix GLP-B for guidance for determining whether to assess the violation as a high, middle, or low level violation).

Each independent violation of the GLP regulations which causes the GLP compliance statement to be false may be assessed as a separate violation of either FIFRA section 12(a)(2)(M) or 12(a)(2)(Q), as appropriate. See the "Multiple Violations" section of this ERP for a further discussion. Also see the July 2, 1990 FIFRA ERP, page 25, for a discussion of independently assessable charges.

Violations of the GLPs Not Related to the GLP Compliance Statement

Certain violations of the GLPs may result in an unlawful act under FIFRA section 12 irrespective and independent of the truthfulness of the GLP compliance statement required by 40 CFR Part 160.12. These unlawful acts include FIFRA sections 12(a)(2)(B)(i); 12(a)(2)(M); 12(a)(2)(Q); and, 12(a)(2)(R).

FIFRA Section 12(a)(2)(B)(i)

Section 12(a)(2)(B)(i) of FIFRA states that it shall be unlawful for any person to refuse to prepare, maintain, or submit any records required under sections 5, 7, 8, 11, or 19. The FIFRA GLP records which registrants, applicants for registration, and producers are required to maintain are, in part, required under the authority of FIFRA section 8. Therefore, failure by a registrant, applicant for registration, or producer to prepare, maintain, or submit any of the records required by the GLPs, including those required under 40 CFR 169.2(k), may be charged as a violation of FIFRA section 12(a)(2)(B)(i).

While almost all of the requirements under the GLPs provide in part for the production and retention of certain records, violations by a registrant, applicant for registration, or producer of the requirements under 40 CFR Part 160.190 - Storage and retrieval of records and data, and Part 160.195 - Retention of records, are particularly associated with recordkeeping and should be assessed as a violation of FIFRA

section 12(a)(2)(B)(i). However, in cases where the raw data or other records are retained, but not according to the requirements in the GLP standards, unlawful acts under FIFRA sections 12(a)(2)(M), 12(a)(2)(Q), or 12(a)(2)(R) should be charged, rather than FIFRA section 12(a)(2)(B)(i).

Because FIFRA section 8 does not currently authorize EPA to require pesticide testing facilities to maintain records, recordkeeping violations by a pesticide testing facility should not be assessed as a violation of FIFRA section 12(a)(2)(B)(i), unless the study is being submitted under FIFRA section 5 for an experimental use permit, or under section 19. Instead, most GLP related recordkeeping or reporting violations by a pesticide testing facility will be charged through enforcement of the truthfulness of the GLP compliance statement (FIFRA sections 12(a)(2)(M) or 12(a)(2)(Q)) or through FIFRA section 12(a)(2)(R).

An unlawful act under FIFRA section 12(a)(2)(M), 12(a)(2)(Q), or 12(a)(2)(R) may be charged in addition to the recordkeeping violation charged under FIFRA section 12(a)(2)(B)(i), if the recordkeeping violation also results in the submission of a false GLP compliance statement (Sections 12(a)(2)(M) or 12(a)(2)(Q)) or the knowing submission of false data (Section 12(a)(2)(R)). The EPA considers these unlawful acts to be independently assessable because it is possible to be in violation of the recordkeeping requirements of the GLPs and still submit a true and correct GLP compliance statement which indicates that the required records have not been maintained. It is also possible to maintain the required records, and therefore comply with section 12(a)(2)(B)(i), but to have maintained false records or to knowingly submit false data to the Agency.

FIFRA Section 12(a)(2)(M)

Section 12(a)(2)(M) of FIFRA states that it shall be unlawful for any person to knowingly falsify all or any part of an application for registration, application for an experimental use permit, any information submitted under section 7, any records required to be maintained by the Act, any report filed under the Act, or any information marked as confidential and submitted to the Administrator under any provision of the Act. Compliance with the GLPs is required as part of an application for registration or an application for an experimental use permit, and GLP compliance entails the maintenance of records (personnel records, Quality Assurance Unit (QAU) records and

reports to management, etc.) and filing of reports (final study reports, including the submission of a GLP compliance statement, QAU reports, etc.). "Knowing falsification" of the GLP records or reports as related to these provisions constitutes a violation of FIFRA section 12(a)(2)(M).

FIFRA Section 12(a)(2)(Q)

Section 12(a)(2)(Q) of FIFRA states that it is unlawful for any person to falsify all or part of any information relating to the testing of any pesticide (or any of its ingredients, metabolites, or degradation products) which the person knows will be furnished to the Administrator, or will become a part of any records required to be maintained by this Act.

Regardless of the truthfulness of the GLP compliance statement, through this unlawful act, EPA may pursue an enforcement action for a violation of any requirement of the GLPs which involves the falsification of testing information which was submitted to the EPA, or for which a testing facility or sponsor knows will eventually be submitted to the Agency, or will be required to be maintained as a record under the GLPs or 40 CFR Part 169. The EPA is not required to assert that the falsification was "knowing," only that the information was "false".

Additionally, under this unlawful act, EPA may pursue an enforcement action for a GLP violation for an ongoing study for which no final report has been submitted to the Administrator and for which no compliance statement under 40 CFR 160.12 has yet been signed, provided the EPA can document that information which was required to be documented as the study proceeded was false, and the pesticide testing facility knew that the information was being generated with the intention of being submitted to the EPA (note the requirement in 40 CFR 160.10). 2/

2/ The appropriate enforcement response for GLP violations in on-going studies will generally be a notice of warning (NOW), unless the violation involves a "knowing" violation. Further, if the violation for which an NOW was issued is not corrected by the time the study is submitted to the Agency, the EPA will pursue a civil or criminal action.

The language of FIFRA section 12(a)(2)(Q) provides this authority since the unlawful act applies to the falsification of information relating to the testing of a pesticide "... that the person knows will be furnished

to the Administrator or will become a part of any records required to be maintained by this Act."

FIFRA Section 12(a)(2)(R)

Section 12(a)(2)(R) of FIFRA states that it is a violation of FIFRA to submit data known to be false in support of a registration. Studies required under FIFRA sections 3, 4, and 24(c) are clearly required to support a pesticide registration. Additionally, studies conducted under FIFRA section 5 and 18 may be used to support a pesticide product registration at some time. Therefore, knowing submission of false data, including false records / reports required under the FIFRA GLPs will constitute a violation of this provision of FIFRA. Unlike FIFRA section 12(a)(2)(Q), the applicability of this unlawful act is dependent on a finding that the data submitted was "known" to be false by the violator.

Multiple Violations

A statement, under 40 CFR 160.12, which certifies that a study complies with the GLPs is a statement that all requirements listed in 40 CFR Part 160 have been met. If requirements of the GLPs have not been met, then the GLP compliance statement is false. Each independent requirement of the GLPs which has been violated, but has been represented through the statement as in compliance, may be considered a separate count of FIFRA section 12(a)(2)(M) or 12(a)(2)(Q), as appropriate, and each count assessed a civil penalty up to the statutory maximum (see the July 2, 1990 FIFRA ERP, page 25, for a discussion of independently assessable charges). For example, a sponsor could be assessed a civil penalty for up to $15,000 because that sponsor submitted a study with a GLP compliance statement which failed to truthfully state that the pesticide testing facility: (1) failed to maintain personnel records; (2) failed to designate a study director; and, (3) failed to record raw data.

Unlawful acts under FIFRA sections 12(a)(2)(B)(i); 12(a)(2)(M); 12(a)(2)(Q); and 12(a)(2)(R) may be assessed in addition to those violations assessed as a false compliance statement, provided that these additional unlawful acts are independent of the counts charged as a falsification of the GLP compliance statement.

Generally, GLP violations will be assessed on a per study basis. Therefore, multiple violations of the same requirement in separate studies will be considered as separate offenses. These violations are

independent violations, and therefore, each violation should be assessed a separate civil penalty of up to the statutory maximum. However, as a matter of policy, multiple violations of the same GLP requirement in a single study will not be assessed as separate offense each time the specific requirement is violated in that study. Rather, multiple violations of the same requirement in a single study will be considered as a single offense which may be raised from a low level to a middle level, or a middle level to a high level GLP violation, depending on the significance and frequency of the violation in a single study (see Appendix GLP-B-2). The Agency has taken this approach for this ERP because many of the GLP requirements which require repetitious compliance throughout the life of the study (such as failing to initial data entries (40 CFR 160.130(e)), can occur unchecked in a single study for an undefined period of time, and penalties for violations of a single repetitive requirement could accumulate to inappropriate or unrealistic levels.

LEVELS OF ACTION

The levels of enforcement action for violations of the FIFRA GLPs include notices of warning, administrative civil penalties, and criminal proceedings. Additionally, in accordance with the July 2, 1990 FIFRA ERP, press releases should be issued in conjunction with most enforcement responses (except notices of warning).

Notices of Warning (NOW)

Notices of Warning (NOW) are the appropriate enforcement response in the following circumstances:

- First-time violations by an independent pesticide testing facility which has been contracted by a study sponsor to conduct testing which falls under the scope of the GLPs. 3/

3/ Pesticide testing facilities which are owned or operated by the registrant may be charged a civil penalty of up to $5,000 per offense for the first violation of the GLPs under FIFRA section 14(a)(1).

Under FIFRA section 14, any person not listed in section 14(a)(1), who is not a "for-hire applicator", may only receive a civil penalty subsequent to receiving a written notice of warning from the Administrator (see page 4 of the

July 2, 1990 FIFRA ERP). Pesticide testing facilities are not included under FIFRA section 14(a)(1) and, therefore, fall under the category of persons under FIFRA section 14(a)(2) who must receive an NOW prior to being assessed a civil penalty for violations of FIFRA.

- o First-time "low level" GLP violations assessed as violations of FIFRA section 12(a)(2)(Q) (see Appendix GLP-B).

- o GLP violations assessed as violations of FIFRA sections 12(a)(2)(B)(i), or 12(a)(2)(R) which are clerical or technical violations which either separately or collectively have a relatively minor impact on: (1) the reliability or scientific merits of the test data; (2) the Agency's ability to make a regulatory decision regarding a pesticide product's registration or other research or marketing permit; (3) the ability of the Agency to be able to validate the test results or reconstruct the study; and, (4) the EPA's administration of the GLP inspection and enforcement program (i.e., impairment of the Agency's inspection targeting ability or the efficienty of the GLP compliance inspections or data audits, etc.). 4/

4/ An example of a clerical or technical violation which has a relatively minor impact on the criteria listed above is a one-time failure to fulfill one of the GLP repetitive requirements, such as, failure to sign or initial, and date a data entry (160.130(e)). Another example is a transcription error which can be verified or corrected by other means and which did not result in an erroneous conclusion for the overall study.

- o Falsification of records required to be maintained in an ongoing study for which not final report has been submitted to the Administrator and for which no compliance statement under 40 CFR 160.12 has yet been signed.

Generally, a notice of warning will not be appropriate if the violator has previously violated the GLP regulations (criteria for establishing "compliance history" may be found in the July 2, 1990 FIFRA ERP, Appendix B, page B-3, footnote number 4) or the violator has received a notice of warning for a previous GLP related violation.

Civil Administrative Penalties

Civil penalties assessed for violations of the FIFRA GLPs are to be calculated according to the procedures and matrices provided in the July 2, 1990 FIFRA Enforcement Response Policy. The gravity levels established for each violation on the FIFRA GLPs are listed in Appendix GLP-A of this ERP and in Appendix A of the July 2, 1990 FIFRA ERP.

Civil penalties may be assessed against both the study sponsor and the pesticide testing facility. A registrant (usually the study sponsor), or pesticide testing facility owned by a registrant, will be assessed civil penalties of up to $5,000 per offense under FIFRA section 14(a)(1). An independent pesticide testing facility who was contracted by the study sponsor will be assessed civil penalties of up to $1,000 per offense, subsequent to a written notice of warning, under section 14(a)(2).

A civil administrative penalty will be issued for all violations of the FIFRA GLPs which do not qualify for a notice of warning and have an impact on: (1) the reliability or scientific merits of the test data; (2) the Agency's ability to make a regulatory decision regarding a pesticide product's registration or other research or marketing permit; (3) the ability of the Agency to be able to validate the test results, i.e., reconstruct study, verify results; or, (4) the EPA's administration of the GLP inspection and enforcement program (i.e., targeting of inspections, delay in an the Agency's inspection activities or data audit because standard GLP procedures or formats are not followed, etc.). In addition, a civil administrative penalty will be issued for repeat violations of the GLP regulations.

Most violations of FIFRA GLP Standards are considered as recordkeeping or reporting violations. As noted in the July 2, 1990 FIFRA ERP, the gravity of recordkeeping and reporting violations are already considered in the dollar amounts presented in the FIFRA civil penalty matrices. Further, recordkeeping and reporting violations do not lend themselves to utilizing the gravity adjustments listed in Appendix B of the July 2, 1990 FIFRA ERP. Therefore, first-time civil penalties are to be assessed at the matrix value, while subsequent civil penalties should be increased by an increment of 30% (up to the statutory maximum). Please note, repeat violations of the identical GLP requirement may indicate a "knowing or willful" violation, and therefore, the need to pursue criminal proceedings.

Criminal Proceedings

Criminal proceedings may be initiated against an applicant for registration, or study sponsor who is a registrant, applicant for registration, or pesticide producer, for knowing and willful violations of the FIFRA GLPs, under FIFRA section 14(b)(1)(A) for criminal penalties of up to $50,000 and/or imprisonment for up to one year. Any commercial applicator of a restricted use pesticide, or any person not described in FIFRA section 14(b)(1)(A) who distributes or sells pesticides or devices, who knowingly violates any provision of FIFRA shall be fined up to $25,000 and/or imprisoned for up to one year. The EPA may also pursue criminal proceedings against the pesticide testing facility, or other person for knowing and willful violations of the GLPs under FIFRA section 14(b)(2) for criminal penalties of up to $1,000 and/or imprisonment for up to 30 days. Additionally, criminal proceedings may be pursued against the registrant, pesticide testing facility, or other person for violating Title 18 of the U.S. Code.

REFERRALS

In addition to the levels of enforcement action listed in the previous section, the EPA may take regulatory action for violations of the GLPs, including: rejection of studies which do not comply with the FIFRA GLPs; cancellation, suspension, or modification of a pesticides research or marketing permit; or denial or disapproval of an application for such a permit. Further, in order to help assure that the Federal Government deals with responsible contractors, and for the purposes of the Federal Government's protection, pesticide testing facilities responsible for significant or major GLP violations may also be suspended or debarred from Government contracts or subcontracts. Until further guidance is issued, the Agency's regulatory response for violations of the GLPs will be addressed on a case-by-case basis and therefore, will not be addressed in detail in this policy.

Office of Pesticide Programs

If the Agency discovers any significant or major GLP violations or data concerns in the course of a facility inspection or study audit, the Office of Compliance Monitoring will notify the Office of Pesticide Programs so that Office may consider if any regulatory action would be appropriate. These regulatory actions include: (1) rejection of studies which do not comply with the FIFRA GLPs; (2) cancellation, suspension, or modification of a pesticide's research or marketing

permit; or, (3) denial or disapproval of an application for such a permit.

Pursuit of an enforcement action by the EPA, such as the issuance of a civil or criminal complaint, does not obligate the Agency to pursue a regulatory response, such as study rejection or cancellation / suspension of a pesticides research or marketing permit. Similarly, a regulatory response by the Agency does not obligate the Agency to pursue an enforcement action. The EPA's decision to pursue an enforcement response and/or regulatory response to a GLP violation will, by administrative necessity, occur on different tracks and will be based on the individual merits of each approach on a case-by-case basis.

Office of Administration

Pesticide testing facilities responsible for significant or major GLP violations may be suspended or debarred from Government contracts, subcontracts, and assistance loan and benefit programs. This action is not for the punishment of the violator nor is it an enforcement tool, but rather it is for the protection of the Federal Government by assuring that the Government will be dealing with responsible contractors.

The Office of Compliance Monitoring will notify the Compliance Branch of the Grants and Administration Division, Office of Administration of the identity of pesticide testing facilities which are responsible for a significant or major GLP violation and have been assessed a civil penalty through a final order or when there is evidence of a criminal offense for violations of the FIFRA GLPs, so that Office may decide whether they wish to pursue suspension or debarment proceedings in accordance with the Federal Acquisition Regulations (FAR) at 48 CFR Subpart 9.4, and the EPA Suspension and Debarment regulations found at 40 CFR Part 32.

APPENDIX GLP - A

FIFRA CHARGES AND GRAVITY LEVELS FOR CIVIL PENALTIES ASSESSED FOR VIOLATIONS OF THE FIFRA GOOD LABORATORY PRACTICE STANDARDS

GLP-A-1

APPENDIX GLP-A

FIFRA CHARGES AND GRAVITY LEVELS

FIFRA SECTION	FITS CODE	VIOLATION	LEVEL
12(a)(2)(B)(i)	2BA	Person refused to PREPARE, MAINTAIN, or SUBMIT any RECORDS required under sections 5, 7, 8, 11 or 19.	2
12(a)(2)(M)	2MA	Person KNOWINGLY FALSIFIED all or any part of an application for registration, application for an experimental use permit, any information submitted under section 7, any records required to be maintained by the Act, any report filed under the Act, or any information marked as confidential and submitted to the Administrator under any provision of the Act.	1
12(a)(2)(Q)	2QA	Person FALSIFIED INFORMATION RELATING to the TESTING of any pesticide (or any of its ingredients, metabolites, or degradation products) for which the person knows will be furnished to the Administrator, or will become a part of any records required to be maintained by this Act.	1
12(a)(2)(Q)	2QB	Person falsely represented compliance with the FIFRA Good Laboratory Practice (GLP) regulations as a result of a HIGH LEVEL GLP* VIOLATION.	2
12(a)(2)(Q)	2QC	Person falsely represented compliance with the FIFRA Good Laboratory Practice (GLP) regulations as a result of a MIDDLE LEVEL GLP* violation.	3
12(a)(2)(Q)	2QD	14(a)(1) person falsely represented compliance with the FIFRA Good Laboratory Practice (GLP) regulations as a result of a LOW LEVEL GLP* violation.	4

12(a)(2)(Q)	2QE	14(a)(2) person falsely represented compliance with the FIFRA Good Laboratory Practice (GLP) regulations as a result of a LOW LEVEL GLP* violation.	3**
12(a)(2)(R)	2RA	Person submitted DATA KNOWN TO BE FALSE in support of a registration.	1

* Guidance on the parameters for determining whether a GLP violation assessed as an unlawful act under FIFRA section 12(a)(2)(Q) is a HIGH, MIDDLE, or LOW LEVEL violation is found in Appendix GLP-B.

** A higher level has been assigned for FIFRA section 14(a)(2) persons because a civil penalty which is assessed under this provision represents the second violation of that person. Violators who fall under the category of persons listed in FIFRA section 14(a)(2) must receive a Notice of Warning for the first GLP violation.

APPENDIX GLP - B

GUIDANCE FOR DETERMINING WHETHER TO ASSESS A GLP VIOLATION UNDER FIFRA SECTION 12(a)(2)(Q) AS A HIGH, MIDDLE, OR LOW LEVEL VIOLATION

APPENDIX GLP-B
GUIDANCE FOR DETERMINING WHETHER TO ASSESS A GLP VIOLATION UNDER FIFRA SECTION 12(a)(2)(Q) AS A HIGH, MIDDLE, OR LOW LEVEL VIOLATION

When assessing a civil penalty for violations of FIFRA section 12(a)(2)(Q) for submission of a false compliance statement (FTTS codes 2QB, 2QC, 2QD, and 2QE, as listed in Appendix GLP-A of this ERP and Appendix A of the July 2, 1990 FIFRA ERP), the parameters listed in this appendix will be used to determine whether a GLP violation is a "high", "middle", or "low level" GLP violation. Because of the expertise that is necessary to make an assessment of the impact of a GLP violation, the determination of whether a violation will be considered as a high, middle, or low level will be made at EPA Headquarters by the Office of Compliance Monitoring with input from the Office of Pesticide Programs and the Office of Enforcement based on the criteria listed in this appendix. A brief summary of the rationale for the categorization of the impact of the GLP violation should be included as part of the civil complaint sent to the respondent.

High Level GLP Violations

A "high level" violation of the FIFRA GLPs involves a substantial failure to comply with the regulations. "High level" GLP violations will have a substantial impact on: (1) the reliability or scientific merits of the test data; (2) the Agency's ability to make a regulatory decision regarding a pesticide product's registration or other research or marketing permit; (3) the ability of the Agency to be able to validate the test results, i.e., reconstruct the study, verify results; or (4) the EPA's administration of the GLP inspection and enforcement program (i.e., impairment of the Agency's inspection targeting ability or the efficiency of the GLP compliance inspections or data audits, etc.). Violations which will be considered as "high level" based on the above criteria include, but are not limited to:

1) Failure to notify a person performing under contract of the applicability of GLPs - Section 160.10.
2) Failure to keep personnel records - Section 160.29.
3) Falsification of personnel records - Section 160.29.
4) Failure to designate a study director - Section 160.31.
5) Failure to assure the existence of a Quality Assurance Unit (QAU) - Section 160.31.
6) Failure of the QAU to conduct any inspections or maintain any records - Section 160.31.

7) Failure to maintain Standard Operating Procedures - Section 160.81.
8) Failure to follow laboratory SOPs without documentation in the raw data and/or written authorization from management - Section 160.81(a).
9) Failure to isolate all newly received animals from outside sources until their health status has been evaluated - Section 160.90(b).
10) Failure to characterize the test, control, or reference substances - Section 160.105.
11) Failure to have a protocol - Section 160.120.
12) Deviation from the protocol without documentation and/or study director written signoff - Section 160.120(b).
13) Failure to record raw data - Section 160.130.
14) Falsification of raw data - Section 160.130.
15) Failure to retain raw data and specimens - Section 160.51, Section 160.190, and Section 160.195.

Partial compliance with a "high level" GLP violation, such as the examples listed above, may justify considering the violations as "middle level" GLP violations.

Middle Level GLP Violations

All violations of GLPs which are not considered "high level" violations are considered to be "middle level" GLP violations UNLESS the violation is determined to be a "low level" violation (see the subsequent section for the criteria for determining a "low level" violation).

Partial compliance with any of the violations which could be considered as a "high level" GLP violation (such as the violations listed in the "High Level GLP Violation section above), may qualify for consideration as a "middle level" GLP violation. For example, a pesticide testing facility may be charged a "middle level" GLP violation rather than a "high level" GLP violation for failure to maintain personnel records, provided that the personnel records for that facility are mostly complete.

Low Level GLP Violations

A GLP violation will be considered "low level" in cases where the violative act was purely clerical or technical in nature with relatively minor impacts on: (1) the reliability or scientific merits of the test data; (2) the Agency's ability to make regulatory decision regarding a pesticide product's registration or other research or marketing permit; (3) the ability of the Agency to be able to validate the test results, i.e., reconstruct the study, verify results; or, (4) the EPA's administration of the GLP inspection and enforcement program (i.e., targeting of inspections, delay in the Agency's inspection or data audit activities because standard GLP procedures or formats are not followed, etc.). "Low level" violations are appropriate where there is a general program in place by a violator to comply with the GLPs, but instances of noncompliance occur anyway due to apparent inadvertent error, equipment failures, or other similar occurrences. Violations which will be considered as "low level" based on the above criteria include, but are not limited to:

1) A facility generally maintained a current summary of training and experience and job description for each individual engaged in the study but failed to do so for one or two individuals

- Section 160.29(b).

2) A facility generally maintained records which documented equipment inspection, maintenance, testing, calibrating, and/or standardizing operations, but failed to document these operations in one instance - 160.63(c).

3) A facility maintained all revisions to the standard operating procedures (SOPs) but failed to note the date of the revision in one or two instances - Section 160.81(d).

4) A reagent or solution which is documented not to degrade does not have an expiration date on the label - Section 160.83.

5) One-time failure to fulfill one of the GLPs repetitive requirements, such as failure to sign or initial, and date a data entry - Section 160.130(e).

6) A clerical error or transposition of numbers in the final study report which can be verified or corrected by other means and which did not result in an erroneous conclusion for the overall study - Section 160.185 or Section 160.195.

If the EPA believes that justice may be served, EPA may issue a Notice of Warning under FIFRA section 9(c)(3) for the first-time "low level" GLP violations. However, subsequent "low level" violations will result in the assessment of a level 4 civil penalty for a FIFRA section 14(a)(1) violator and a level 3 civil penalty for a FIFRA section 14(a)(2) violator.